Midterm results of a precuffed expanded polytetrafluoroethylene graft for above knee femoropopliteal bypass in a multicenter study

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Introduction: **Above knee (AK) femoropopliteal bypass remains a sufficient and durable therapy for long occlusions of the superficial femoral artery in the era of endovascular repair. A novel, precuffed expanded polytetrafluoroethylene (ePTFE) graft that was designed for AK femoropopliteal bypass (Dynaflo, Bard Peripheral Vascular Inc, Tempe, Ariz) has been available for clinical use since March 2005, promising better patency rates by optimizing the hemodynamic patterns within the distal anastomosis.**

Methods: **A prospective, multicenter, nonrandomized study was performed to investigate the clinical results of the Dynaflo graft. Primary end points were patency rates, limb salvage, and complications.**

Results: **Between March 2005 and August 2007, the Dynaflo graft was used in 135 AK bypasses in 134 patients (110 men) with a mean age of 66 years. Indication for revascularization was claudication in 99 (73%) and critical ischemia in 36 (27%). With a mean follow-up of 18 months the 6-, 12- and 24-month primary patency rates were 90%, 83% and 72.5% and the secondary patency rates were 93%, 88.6% and 82.2%, respectively. The cumulative limb salvage rate at 24 months was 95%. Complications were observed in 39 patients (29%), with bypass failure (29 cases) and significant thrombus accumulation at the distal anastomosis (4 cases) being the most severe.**

Conclusion: **This study presents the first clinical results of a novel ePTFE graft for supragenicular revascularization. The implantation of the Dynaflo graft seems to be safe and feasible for AK bypass, achieving acceptable medium-term patency rates. Nevertheless, long-term results have to be awaited, and prospective comparative studies are warranted. (J Vasc Surg 2009;49:1203-9.)**

Infrainguinal femoropopliteal above knee (AK) bypass for the treatment of peripheral arterial disease (PAD) with long occlusion, defined as TransAtlantic Inter-Society Consensus (TASC) II C lesions of the superficial femoral artery (SFA), has better long-term results than percutaneous transluminal angioplasty (PTA).[1] Autologous great saphenous vein is the optimal graft material for below knee (BK) as well as AK femoropopliteal reconstructions.[2-4] Absence of suitable vein or choice of the surgeon to preserve the vein for future revascularizations prompts the use of prosthetic grafts.

Efforts to improve the patency rates of the established femoropopliteal bypasses with expanded polytetrafluoroethylene (ePTFE) or Dacron grafts have been made by modifying the inner surface of ePTFE or Dacron (heparin-bonded grafts), or by use of human umbilical vein (HUV).[4-6] The interposition of vein at the distal anastomosis of prosthetic bypasses is reported to improve patency rates of infragenicular bypasses by optimizing the hemodynamic patterns.[7,8]

Precuffed BK femoropopliteal grafts seem to achieve similar patency rates compared with vein-cuff interposition at the distal anastomosis.[9,10] The same principle of precuffed distal anastomosis was introduced for AK femoropopliteal bypasses with the Dynaflo graft (Bard Peripheral Vascular Inc, Tempe, Ariz; Fig 1). This study reports the first early clinical results of a prospective multicenter cohort study with this novel graft.

MATERIALS AND METHODS

Study design. A prospective, multicenter, nonrandomized study was performed to investigate the clinical results of the new Dynaflo prosthetic graft for AK bypass (Fig 1). The study included all consecutive adult patients with claudication (Rutherford 2 to 3) or chronic critical limb ischemia (Rutherford 4 to 6) who were considered suitable for elective revascularization by use of a supragenicular prosthetic bypass graft, provided the patients had given written consent to take part in the study and in follow-up. Primary end points were patency rates, limb salvage, and complications.

Patients with claudication were only included after completion of exercise training without sufficient improvement (>50%) and when no percutaneous treatment (an-

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Fig 1. Dynaflo (Bard Peripheral Vascular Inc, Tempe, Ariz) expanded polytetrafluoroethylene graft with the precuffed distal end designed to optimize hemodynamics within the distal end-to-side anastomosis.

gioplasty with or without stent implantation) was feasible or reasonable with respect to long-term results.

All patients were presented in an interdisciplinary conference with vascular surgeons, angiologists, and interventional radiologists because certified vascular centers in Germany are obligated to discuss less invasive therapeutic options. To achieve homogeneity in the group of patients undergoing AK femoropopliteal bypass between the three centers, no patients with an occlusion length of the superficial femoral artery of <15 cm were included before undergoing an endovascular approach.

A relevant (>50%) stenosis of the deep femoral artery that could be treated with patch angioplasty or another reconstruction was an exclusion criterion. A nonseverely calcified segment of adequate length of the proximal popliteal artery, as estimated by the surgeon, had to be available to ensure an exact configuration of the cuff without modification. Adequate inflow to the common femoral artery was a prerequisite for inclusion in the study. If not present or if at least improvable, adequate inflow had to be established before or during the operation. Adequate inflow was considered present when triphasic flow in the common femoral artery was found using color-coded Doppler ultrasound imaging or when the iliac vessels were angiographically free of >30% stenosis or multiple stenoses. The Dynaflo grafts were implanted by the 11 vascular surgeons of the participating centers as well as by five vascular trainees under supervision.

Other exclusion criteria were emergency operation, pregnancy, malignant disease, short (<1 year) life expectancy, popliteal aneurysmal disease, and extended infection of the affected limb, which might put the implanted graft at risk of infection.

Preoperative assessment. The PAD-specific preoperative workup of the patients included evaluation of ankle-brachial index (ABI), free-of-pain walking distance on the treadmill with 3 km/h speed and 12% inclination for patients with claudication, and conventional digital subtraction angiography (DSA). DSA was the preferred preoperative imaging modality in patients who were planned to undergo surgical treatment, but computer tomography angiography (CTA; n = 1) or magnetic resonance angiography (MRA; n = 5) were also accepted in selected cases. The inflow to the common femoral artery was assessed either with color-coded Doppler ultrasound imaging (triphasic flow) when only a fine-needle angiography had been performed as preoperative diagnostic modality of the affected limb or angiographically when angiography of the aortoiliac vessels was available.

Operation. The popliteal artery was exposed in its first segment by a supragenicular medial approach. Inspection and palpation confirmed its suitability as a recipient artery for an AK bypass. Exposure of the common femoral as well as the proximal deep femoral artery and the proximal SFA was performed by an infrainguinal incision. The Dynaflo graft was implanted extra-anatomically or anatomically with the help of a tunneling instrument, preventing kinking of the graft proximal to the distal cuff. Systemic heparin was administered at a dose of 5000 IU, and the popliteal artery was clamped.

After longitudinal arteriotomy, the distal anastomosis was performed with a running Prolene 5-0 suture (Ethicon, Norderstedt, Germany). The length of popliteal arteriotomy was adapted carefully to the requirements of an optimal cuff configuration during the suturing. In these procedures, the precuffed end of the graft should not be modified in any way. The arteriotomy was performed long enough so that the whole cuff could be sewn without modification. In particular, the arteriotomy must not be too long, because this would stretch the cuff on the longitudinal axis and could compromise the cuff in the transverse axis. No exact length of required popliteal artery was defined in the protocol, and the decision concerning the length of the arteriotomy as well as the further technique for the suture of the cuff was left at the discretion of the surgeon. An intraoperative angiogram was obligatory only when an intraoperative technical error was suspected or when a more proximal stenosis (not identified preoperatively) was assumed during the flushing maneuver from the common femoral artery.

The proximal anastomosis was performed end-to-side with the common femoral artery. When necessary, adequate inflow was established before the bypass by intraoperative balloon angioplasty or retrograde disobliteration of the iliac vessels.

Postoperative care and follow-up. On postoperative day 3 to 5, all patients underwent a control DSA of the operated-on limb when no intraoperative angiography had been performed (Fig 2). An intraoperative angiography was not obligatory according to the study protocol, and the decision was left to surgeon's discretion.

All patients received anticoagulation for 2 days postoperatively with low-molecular-weight heparin at a prophylactic dose of dalteparin at 5000 IU per day. On the third postoperative day, when no contraindications such as major wound healing disorder or another planned operation were present, further anticoagulation was initiated with anti-

Fig 2. Postoperative digital subtraction angiography of the left limb, with focus on the distal precuffed end-to-side anastomosis.

platelet agents or warfarin. Heparin was continued until antiplatelet or warfarin therapy reached effective levels. The standardized postoperative anticoagulation scheme included daily antiplatelet therapy (100 mg of aspirin or 75 mg of clopidogrel in cases of aspirin intolerance) when two or more tibial or peroneal vessels were patent. When balloon angioplasty with a stent was performed intraoperatively, clopidogrel was added to the aspirin anticoagulation for 6 weeks.

Daily warfarin derivatives were administered to compliant patients with only one patent crural vessel, even when they presented with claudication or after revision for bypass occlusion or thrombus formation at the distal anastomosis and when no contraindications were present (optimal international normalized ratio of 2.5 to 3.5). Patients with prior dual antiplatelet therapy with aspirin and clopidogrel because of coronary stents were prescribed oral anticoagulation, if needed according to protocol, only after consultation with cardiologists.

The follow-up protocol included office visits, clinical examination with recording of ABI, and color-coded duplex ultrasound imaging at 3, 6 and 12 months postoperatively and every 6 months thereafter. Patients' data were collected in a SPSS 14.00 database (SPSS Inc, Chicago, Ill). Kaplan-Meier survival analysis for primary outcome parameters was performed with Stata 10.0 (StataCorp, College Station, Tex).

Table I. Demographics and risk factors of 134 patients assigned to receive an above-knee graft[a]

Risk factor	*No. of grafts (n = 135) or mean value*	*Percentage[b] or range*
Patient age, y	66	39-86
Male	110	81
Female	25	19
PAD stage		
Claudication	99	73
Critical limb ischemia	36	27
SFA occlusion ≥20 cm	125	92.6
Coronary artery disease	48	36
Prior myocardial infarction	30	22
Diabetes mellitus	42	31
Noninsulin dependent	23	17
Insulin dependent	19	14
Hypertension	113	84
Hyperlipidemia	56	42
Current and former smokers	104	77
Current smokers	71	53
Renal insufficiency	31	23

PAD, Peripheral arterial disease; *SFA,* superficial femoral artery.
[a]One patient received a bilateral graft implantation.
[b]N = 135 grafts, according to 100%.

RESULTS

Between March 2005 and August 2007, 135 AK femoropopliteal bypasses were implanted in 134 patients (110 men) using the Dynaflo graft in three vascular centers in Germany (Fig 1). Table I summarizes the demographics and cardiovascular risk factors of the group, typical for patients with PAD. The overall mean patient age was 66 years (range, 39-86 years). Before surgery, 112 patients (83%) were receiving antiplatelet therapy with aspirin, 60% were receiving angiotensin-converting enzyme inhibitors, and 58% were receiving β-blockers. The mean preoperative serum creatinine value was 1.1 mg/dL (range, 0.5-2.7; normal value <1.3 mg/dL).

Prior revascularization of the ipsilateral limb or iliac arteries had been done in 39 cases (29%), as summarized in Table II. Six patients (4.6%) had undergone minor amputation of the affected limb before bypass graft implantation. The patients with claudication had a mean preoperative ABI of 0.6 (range, 0.2-1.1), and those with critical limb ischemia had a mean ABI of 0.3 (range, 0,1-0,6). Five patients (5.1%) were excluded from the calculation of mean ABI because of an ABI >1.5 and renal insufficiency or diabetes mellitus due to media sclerosis. The mean preoperative free-of-pain walking distance in the patients with intermittent claudication was 90 m (range, 10-200 m).

A patent BK popliteal artery was a requirement to perform AK revascularization. In 77 extremities (57%), all

Table II. Revascularization procedures of the affected limb preceding the above knee bypass

Interventions/operations	*No.*	*%*
None	96	71
PTA with or without stent		
Of the SFA	10	7
Of iliac arteries	15	11
Femoral artery patch angioplasty	7	5
Aortobifemoral bypass	7	5
AK femoropopliteal bypass	2	1.5

AK, Above knee; *PTA*, percutaneous transluminal angioplasty; *SFA*, superficial femoral artery.

three crural vessels were patent, whereas 33 (24%) had two, and 25 (19%) had only one patent tibial or peroneal vessel. In 88% of the grafts, the diameter was 7 mm, and only 12% had an 8-mm diameter. The surgeon decided the diameter of the graft according to the diameter of the common femoral and the recipient artery. None of the grafts was ringed.

In addition to the femoropopliteal bypass, 12 patients (9%) required an intraoperative optimization of inflow to the common femoral artery through balloon angioplasty or retrograde ring-assisted endarterectomy and angioplasty of the iliac arteries. No complications affecting the outcome of the femoropopliteal bypass resulted from the intervention on the iliac arteries.

Intraoperative angiography was done in 31 of the 135 limbs, and the remaining 104 had fine-needle angiography on postoperative day 3 to 5. No technical errors were identified in the postoperative angiogram and therefore no early elective revisions required. At the time of dismissal, 81 patients (60%) were receiving anticoagulation with antiplatelet agents (aspirin or clopidogrel), 41 (30%) had a combination of aspirin and clopidogrel, and 12 (9%) were receiving oral warfarin. Two patients in our series had prior oral anticoagulation, so that a total of 10 patients (7.4%) had a change of anticoagulation to warfarin derivatives postoperatively.

During follow-up, the anticoagulation was changed from antiplatelet agents to warfarin derivatives in 11 patients. The indication was bypass occlusion with revision in order to preserve secondary patency in five patients at 7, 8, 11, 13, and 17 months, respectively, and thrombus in the distal anastomosis with high risk of distal embolization or occlusion in another patient at 12 months. The remaining four patients received warfarin derivatives for cardial indication between 6 and 18 months postoperatively.

Complications were observed in 39 patients (29%), with bypass failure (29 cases) and thrombus accumulation at the distal anastomosis (4 cases) being the most severe. No bypass infection was reported. Minor complications included wound infection (5%), postoperative hematoma (3%), and perigraft seroma formation (2%). Six patients (4.4%) died during follow-up, and one died ≤30 days postoperatively for an operative mortality rate of 0.7%.

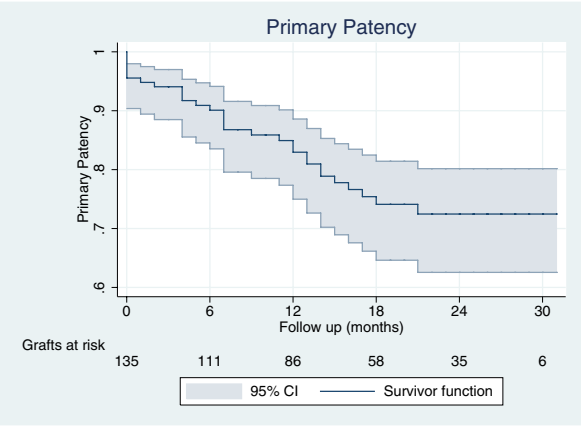

Fig 3. Cumulative primary patency after above knee bypass with the Dynaflo (Bard Peripheral Vascular Inc, Tempe, Ariz) graft using Kaplan-Meier analysis.

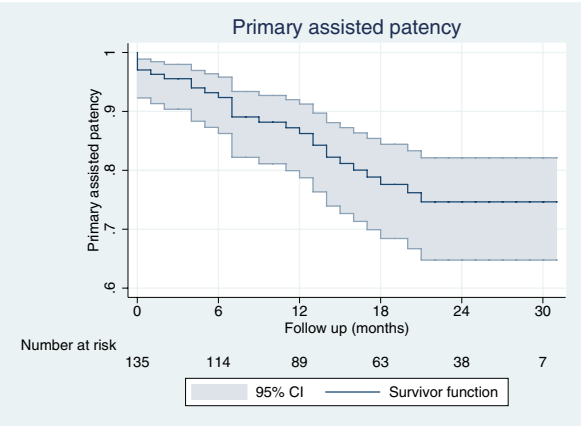

Fig 4. Cumulative assisted primary patency after above knee bypass with the Dynaflo (Bard Peripheral Vascular Inc, Tempe, Ariz) graft using Kaplan-Meier analysis.

Graft patency. After a mean follow-up of 18 months (range, 1-31 months) 29 grafts had failed, defined as occlusion or intervention was required to preserve patency. The cumulative primary patency rate of the Dynaflo graft at 6, 12, 18, and 24 months was 90%, 83%, 74%, and 72.5%, respectively (Fig 3). The Kaplan-Meier analysis tables are available in Appendices I-III (online only). Four patients underwent reoperation or a change in anticoagulation therapy to preserve patency, so that the primary assisted patency rates at 6, 12, 18, and 24 months were 92.4%, 86.2%, 77.6%, and 74.6%, respectively (Fig 4). In one patient with a potentially failing graft, thrombus material was removed from the distal anastomosis by thrombectomy. Two patients underwent surgery to optimize inflow, and another patient's anticoagulation was changed to oral warfarin because of thrombus material in the distal anastomosis. One of the two surgically treated patients had a severe stenosis of the common femoral artery above the proximal anastomo-

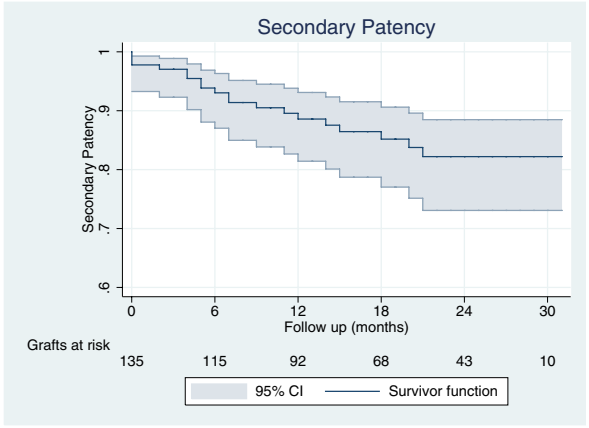

Fig 5. Cumulative secondary patency after above knee bypass with the Dynaflo (Bard Peripheral Vascular Inc, Tempe, Ariz) graft using Kaplan-Meier analysis.

sis, requiring endarterectomy and patch angioplasty extending to the proximal anastomosis. The second patient had stenosis of the external iliac artery and the common femoral artery on 1-year follow-up, which was treated with a hybrid procedure of balloon angioplasty and stent of the iliac artery and patch angioplasty of the common femoral artery.

Secondary procedures included simple thrombectomy in six patients (4.4%), thrombectomy with revision of the distal anastomosis in another six (4.4%), and a redo procedure with BK revascularization in three (2.2%). The latter three patients with occluded Dynaflo grafts were considered secondary failures and excluded from further evaluation in the study. Ten patients (7.4%) with bypass occlusion and stable claudication were managed conservatively. The resulting secondary patency rates at 6, 12, 18 and 24 months were 93%, 88.6%, 85.2%, and 82,2%, respectively (Fig 5).

ABI and walking distance. The mean postoperative ABI of the entire group was 1.2 (range, 0.7-1.5). Claudicant patients had a mean postoperative ABI of 1.2 (range, 0.9-1.5), and patients with critical ischemia had a postoperative mean ABI of 1.0 (range, 0.7-1.2). The postoperative measurement of free-of-pain walking distance on the treadmill was discontinued when the patient was free of pain after 200 m. This occurred in 55% of the claudication patients postoperatively. The mean postoperative free-of-pain walking distance of the rest of this group was 112 m (range, 50-200 m).

Wound healing and limb salvage. Among the 36 patients with critical limb ischemia, 25 had ulcers or gangrene and 11 had pain at rest. Postoperative improvement of pain occurred in all but one of these 11 patients. This patient had a vital extremity with good perfusion, and the analgetic therapy was extended. The median visual analog scale score for pain was 7 preoperatively and 3 at 1 week postoperatively. Among the 25 extremities with ulcers or gangrene, complete healing of the wounds was achieved ≤4 weeks postoperatively in 14 cases, whereas nine patients required minor amputation. Despite a functioning bypass, one patient required a BK amputation early postoperatively. No healing disorders of the amputation wounds were observed. The remaining patient had a chronic wound that did not heal despite adequate revascularization and received further conservative treatment.

Seven limbs (5%) were unsalvageable, and major amputation was performed despite a patent graft in two. The primary indication for revascularization of these limbs was critical limb ischemia in five and claudication in two. The cumulative 24-month limb salvage rate was 95% in the entire group of patients independent of the PAD stage and 86% in the subgroup of 36 patients with critical limb ischemia.

DISCUSSION

In the era of endovascular therapy with the application of innovative techniques such as subintimal recanalization, laser-assisted techniques, and flexible or covered stents in the area of the SFA, conventional vascular surgery appears to be on the decline.[11-16] Nevertheless, although the idea of achieving endovascular recanalization of the SFA also in TASC C and D lesions and reserving surgery for cases of failed endovascular therapy is appealing, no randomized controlled studies have compared bypass with PTA to give a reliable answer. To date, long-term results of PTA are still inferior to surgery.[1] Therefore, femoropopliteal bypass remains the gold standard in most vascular centers for chronic occlusions of the SFA that are >20 cm.

The discussion about the best bypass material seems to have been answered: Several studies, including two published meta-analyses, proved the superiority of vein, even for AK bypasses.[2-4] Nevertheless, many vascular surgeons are reluctant to use an available great saphenous vein for AK revascularization because of the potential future need for a more distal BK revascularization.

The ideal vascular bypass graft should replicate the mechanical properties of native artery perfectly to maximize patency. In particular, it would demonstrate viscoelasticity for efficient pulsatile flow, matched compliance to prevent intimal hyperplasia, and have a burst pressure well above the physiologic range of hemodynamic pressures.[17] An extensive body of literature describing effects of laminar shear stress on endothelial cells has contributed to our understanding of the interactions between shear stress and blood vessels. Laminar shear stress is atheroprotective, whereas oscillatory or disturbed shear stress correlates with areas of atherosclerosis and intimal hyperplasia in vivo.[18]

The compliance mismatch between a vascular graft and the native arterial wall also has a similar effect on intimal hyperplasia formation. The role of flow stagnation is widely accepted as a risk factor for intimal hyperplasia development due to a low level of wall shear stress applied at certain areas of the terminolateral anastomosis. Points subjected to flow stagnation in the anastomosis include the floor, toe, and heel of the anastomosis.[19,20]

The rationale behind the Distaflo graft is that of suppression of intimal hyperplasia through optimization of hemodynamic forces within the distal end-to-side anastomosis and is based on evidence of an inverse relationship between mean wall shear stress and intimal hyperplasia.[8,21,22]

The vortex, deemed to be beneficial in the Miller cuff, has been replicated in most of the in vivo Distaflo grafts, which are widely used as an alternative to interposition of vein in the treatment of critical limb ischemia.

The Dynaflo graft represents the modification of Distaflo for AK bypass procedures preserving the same precuffed form in the distal anastomosis. Only minor further modifications were made to adjust the Dynaflo graft to the AK segment of the popliteal artery. The larger cuff increases the flow potential of the graft for larger anastomotic sites such as found in a femoropopliteal AK bypass.

Two clinical trials demonstrated noninferiority concerning primary and secondary graft patency and limb salvage rates when comparing a precuffed ePTFE graft (Distaflo, Bard Peripheral Vascular Inc, Tempe, Ariz) with a vein-cuffed ePTFE graft for infragenicular arterial bypasses.[9,10] Satisfactory patency rates have also been described for the Distaflo graft in several other studies.[23-25] The 5-year patency rate of ePTFE AK femoropopliteal bypass is between 35% and 52% in randomized trials, with vein achieving cumulative patency rates of 74% to 76%.[1,3,5,26,27] The configuration of the distal cuff of the Dynaflo graft (Bard Peripheral Vascular Inc, Tempe, Ariz) aims at improving patency rates of AK femoropopliteal bypass by optimizing the hemodynamics through anastomotic engineering of the distal anastomosis.

In the present prospective multicenter study, the cumulative primary and secondary patency at 24 months of follow-up were 72.5% (confidence interval [CI], 62.6-80.2%) and 82% (CI, 73.1-88.5%) respectively. Intermittent claudication was present in 73% of the patients in the present cohort, which also explains the low 5% rate of major amputation in our series. Nevertheless, two limb losses occurred in patients with intermittent claudication before the primary operation. Both patients presented on follow-up with progressive infrapopliteal atherosclerotic disease and bypass occlusion. In one patient embolization of the tibial vessels from a thrombus in the graft cuff was suspected.

Four patients in the present series were diagnosed with relevant thrombus formation in the cuff of the distal anastomosis. In two patients the thrombus mass was limited and required no intervention. One patient was treated with oral anticoaglation, and the remaining patient underwent bypass revision.

The graft managed with life-long oral anticoagulation was considered a failing graft (primary patency failure) because a prophylactic although nonsurgical intervention was required, which nevertheless has an important consequence on the patient's quality of life.

Formation of thrombus in the cuff of the distal anastomosis could be a drawback of the Dynaflo prosthesis. Furthermore in our experience, surgical thrombectomy of an occluded graft frequently required revision of the distal anastomosis to fully extract the thrombus mass from the cuff, which was difficult to achieve over an inguinal approach with a Fogarty maneuver only. An intraoperative DSA was considered obligatory for the same reason.

The Dynaflo graft is thinner ePTFE in the area of the graft cuff, which might provide better viscoelastic properties and better compliance. Because of this property of the cuff, especially careful handling of the graft during suture of the distal anastomosis is needed.

Major drawbacks of our study are its descriptive character and the lack of a control group of patients undergoing implantation of another bypass graft. Data from other studies as well as meta-analyses are available, however, and cautious comparison of these data with the results of the present study seems to be reasonable. Thus in several studies, ePTFE achieved cumulative patency rates of 50% to 77% after 2 years of follow-up.[5,27-29]

Klinkert et al[2] reported in their meta-analysis cumulative primary patency rates of 67% for ePTFE grafts (2520 grafts) at 2 years of follow-up when all studies were reviewed and 69% (643 grafts) when only randomized controlled trials were included. Therefore, considering the limitations of our study, we can cautiously conclude that with 72.5% primary and 82% secondary cumulative patency, the Dynaflo graft seems to perform at least equally at 2 years of follow-up compared with standard ePTFE grafts.[2]

Randomized controlled trials, based on the results obtained in the present study, are warranted because only these type of high-level evidence studies, including later meta-analyses, can definitely answer the everlasting question of the best conduit for AK femoropopliteal bypass.

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AUTHOR CONTRIBUTIONS

Conception and design: RR,* NT,* BL, MS
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Writing the article: NT, RR
Critical revision of the article: RR, NT, BL, JW, GS, MS
Final approval of the article: RR, NT, BL, JW, GS, MS
Statistical analysis: NT
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*RR and NT contributed equally to this article.

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Appendix I (online only). Kaplan-Meier analysis table for primary patency

Time, months	*Total, No.*	*Failed, No.*	*Lost, No.*	*Function*	*Error*	*95% CI*
.01	135	6	0	0.9556	0.0177	0.9038-0.9798
1	129	1	0	0.9481	0.0191	0.8943-0.9749
2	128	1	4	0.9407	0.0203	0.8850-0.9699
3	123	0	3	0.9407	0.0203	0.8850-0.9699
4	120	3	4	0.9172	0.0239	0.8554-0.9533
5	113	1	1	0.9091	0.0251	0.8454-0.9474
6	111	1	1	0.9009	0.0261	0.8353-0.9413
7	109	4	4	0.8679	0.0299	0.7958-0.9158
8	101	0	4	0.8679	0.0299	0.7958-0.9158
9	97	1	2	0.8589	0.0309	0.7851-0.9088
10	94	0	4	0.8589	0.0309	0.7851-0.9088
11	90	1	3	0.8494	0.0320	0.7735-0.9014
12	86	2	1	0.8296	0.0342	0.7498-0.8859
13	83	2	3	0.8096	0.0362	0.7263-0.8698
14	78	2	4	0.7889	0.0381	0.7022-0.8529
15	72	1	4	0.7779	0.0391	0.6894-0.8440
16	67	1	3	0.7663	0.0402	0.6758-0.8346
17	63	1	4	0.7541	0.0414	0.6616-0.8247
18	58	1	6	0.7411	0.0427	0.6462-0.8142
19	51	0	1	0.7411	0.0427	0.6462-0.8142
20	50	0	5	0.7411	0.0427	0.6462-0.8142
21	45	1	3	0.7247	0.0448	0.6256-0.8016
22	41	0	3	0.7247	0.0448	0.6256-0.8016
23	38	0	3	0.7247	0.0448	0.6256-0.8016
24	35	0	3	0.7247	0.0448	0.6256-0.8016
25	32	0	8	0.7247	0.0448	0.6256-0.8016
26	24	0	2	0.7247	0.0448	0.6256-0.8016
27	22	0	5	0.7247	0.0448	0.6256-0.8016
28	17	0	6	0.7247	0.0448	0.6256-0.8016
29	11	0	5	0.7247	0.0448	0.6256-0.8016
30	6	0	5	0.7247	0.0448	0.6256-0.8016
31	1	0	1	0.7247	0.0448	0.6256-0.8016

CI, Confidence interval.

Appendix II (online only). Kaplan-Meier analysis table for primary assisted patency

Time, months	*Total, No.*	*Failed, No.*	*Lost, No.*	*Function*	*Error*	*95% CI*
.01	135	4	0	0.9704	0.0146	0.9230-0.9888
1	131	1	0	0.9630	0.0163	0.9133-0.9844
2	130	1	4	0.9556	0.0177	0.9038-0.9798
3	125	0	3	0.9556	0.0177	0.9038-0.9798
4	122	2	4	0.9399	0.0206	0.8834-0.9695
5	116	1	1	0.9318	0.0220	0.8729-0.9639
6	114	1	1	0.9236	0.0233	0.8626-0.9582
7	112	4	4	0.8906	0.0277	0.8221-0.9338
8	104	0	4	0.8906	0.0277	0.8221-0.9338
9	100	1	2	0.8817	0.0288	0.8112-0.9271
10	97	0	4	0.8817	0.0288	0.8112-0.9271
11	93	1	3	0.8722	0.0300	0.7995-0.9199
12	89	1	1	0.8624	0.0312	0.7874-0.9124
13	87	2	2	0.8426	0.0335	0.7634-0.8970
14	83	2	4	0.8223	0.0356	0.7393-0.8810
15	77	1	4	0.8116	0.0367	0.7267-0.8725
16	72	1	3	0.8004	0.0379	0.7133-0.8635
17	68	1	4	0.7886	0.0391	0.6992-0.8541
18	63	1	6	0.7761	0.0405	0.6843-0.8442
19	56	0	1	0.7761	0.0405	0.6843-0.8442
20	55	1	5	0.7620	0.0421	0.6670-0.8332
21	49	1	3	0.7464	0.0440	0.6477-0.8212
22	45	0	4	0.7464	0.0440	0.6477-0.8212
23	41	0	3	0.7464	0.0440	0.6477-0.8212
24	38	0	3	0.7464	0.0440	0.6477-0.8212
25	35	0	8	0.7464	0.0440	0.6477-0.8212
26	27	0	2	0.7464	0.0440	0.6477-0.8212
27	25	0	6	0.7464	0.0440	0.6477-0.8212
28	19	0	7	0.7464	0.0440	0.6477-0.8212
29	12	0	5	0.7464	0.0440	0.6477-0.8212
30	7	0	6	0.7464	0.0440	0.6477-0.8212
31	1	0	1	0.7464	0.0440	0.6477-0.8212

CI, Confidence interval.

Appendix III (online only). Kaplan-Meier analysis table for secondary patency

Time, months	*Total, No.*	*Failed, No.*	*Lost, No.*	*Function*	*Error*	*95% CI*
.01	135	3	0	0.9778	0.0127	0.9327-0.9928
2	132	1	4	0.9704	0.0146	0.9230-0.9888
3	127	0	3	0.9704	0.0146	0.9230-0.9888
4	124	2	4	0.9547	0.0181	0.9019-0.9794
5	118	2	1	0.9385	0.0211	0.8808-0.9688
6	115	1	1	0.9304	0.0224	0.8703-0.9632
7	113	2	4	0.9139	0.0249	0.8498-0.9514
8	107	0	4	0.9139	0.0249	0.8498-0.9514
9	103	1	2	0.9050	0.0262	0.8386-0.9450
10	100	0	4	0.9050	0.0262	0.8386-0.9450
11	96	1	3	0.8956	0.0275	0.8266-0.9382
12	92	1	1	0.8859	0.0289	0.8143-0.9310
13	90	0	5	0.8859	0.0289	0.8143-0.9310
14	85	1	4	0.8755	0.0304	0.8011-0.9233
15	80	1	4	0.8645	0.0319	0.7872-0.9152
16	75	0	3	0.8645	0.0319	0.7872-0.9152
17	72	0	4	0.8645	0.0319	0.7872-.09152
18	68	1	6	0.8518	0.0339	0.7704-0.9060
19	61	0	1	0.8518	0.0339	0.7704-0.9060
20	60	1	5	0.8376	0.0362	0.7515-0.8959
21	54	1	3	0.8221	0.0387	0.7307-0.8848
22	50	0	4	0.8221	0.0387	0.7307-0.8848
23	46	0	3	0.8221	0.0387	0.7307-0.8848
24	43	0	3	0.8221	0.0387	0.7307-0.8848
25	40	0	9	0.8221	0.0387	0.7307-0.8848
26	31	0	2	0.8221	0.0387	0.7307-0.8848
27	29	0	7	0.8221	0.0387	0.7307-0.8848
28	22	0	7	0.8221	0.0387	0.7307-0.8848
29	15	0	5	0.8221	0.0387	0.7307-0.8848
30	10	0	9	0.8221	0.0387	0.7307-0.8848
31	1	0	1	0.8221	0.0387	0.7307-0.8848

CI, Confidence interval.